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|--|---------------|-------------------------|---------------------|------------------|
| APPLICATION NO.  | FILING DATE   | FIRST NAMED INVENTOR    | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/699,098   | 10/30/2003    | Florenziano Della Torre | I/4659-2            | 2668             |
| 2352   | 7590          | 05/16/2008              | EXAMINER            |                  |
| OSTROLENK FABER GERB & SOFFEN<br>1180 AVENUE OF THE AMERICAS<br>NEW YORK, NY 100368403 |               |                         | DEAK, LESLIE R      |                  |
| ART UNIT   | PAPER NUMBER  |                         |                     |                  |
|  | 3761          |                         |                     |                  |
| MAIL DATE  | DELIVERY MODE |                         |                     |                  |
| 05/16/2008   | PAPER         |                         |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                                      |   |
|------------------------------|--------------------------------------|---|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/699,098 | <b>Applicant(s)</b><br>TORRE, FLORENZIANO DELLA |
|                              | <b>Examiner</b><br>LESLIE R. DEAK    | <b>Art Unit</b><br>3761                         |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05 March 2008.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 8-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 8-10 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 30 October 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-146/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,561,997 to Weitzel et al in view of US 4,828,543 to Weiss et al.

In the specification and figures, Weitzel discloses the device substantially as claimed by applicant. With regard to claim 8, Weitzel discloses a hemofiltration or dialysis system that acts as a renal assist device (see column 2, lines 15-20). The apparatus comprises a hemofiltration system 300 with a blood path or connecting means 58/72 that connects to pass blood to and from a patient 100, pump or blood processing means 52, a container 60 and pump 56 for infusing anticoagulant (corresponding to applicant's means for adding drugs), containers 62, 64, pump 56 for replacement fluid (corresponding to applicant's means for feeding refill liquid), and blood filter 48 (see FIG 1, column 4, line 40 to column 5, lines 20).

Weitzel fails to disclose an oxygenating device connected upstream of the blood filter and a programmable controller. However, Weiss discloses an extracorporeal treatment device that uses mass transfer devices such as filters and oxygenators to withdraw, treat, and return blood to the patient. In particular, the device seeks to circulate, cleanse, and oxygenate a patient's blood in the event of blood system failure

(see column 1, line 63 to column 2, line 11). The apparatus includes a blood path (see line 102 in FIG 9), pumps 104, 106, and treatment means connected in series (142A, 142B, 142C). The treatment means may comprise blood filters or a blood oxygenator (see column 25, line 35 to column 26, line 52, column 32, lines 12-14). The treatment means connected in series (wherein the oxygenator may be located upstream of the filter) allow for a combination of a plurality of treatments that replace a patient's damaged blood system (see column 26, lines 37-52, column 1, line 63 to column 2 line 11). Weiss further discloses that the apparatus comprises a programmable controller 210 that acts to manipulate the transmembrane pressure, by adjusting pump speeds, which, in turn, affects the filtration rate and rate of removal of fluid from the patient (see column 2, line 48 to column 3, line 45, column 8, line 44 to column 9, line 25). Accordingly, the controller disclosed by Weiss is capable of being programmed with information for setting a total fluid loss and rate of fluid loss as claimed by applicant. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add an oxygenator upstream of the filter as disclosed by Weiss in the apparatus disclosed by Weitzel in order to provide a plurality of treatments to replace the function of a patient's damaged blood system, as taught by Weiss.

With regard to applicant's claim drawn to the operation of the pump, applicant claims the operation of the blood pump to create a particular flow rate. Such a limitation is considered by the examiner to be a statement of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed fails to differentiate the claimed apparatus from a prior art

apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Weitzel specifically discloses that the blood pump 52 may be set to pump blood at a rate of 10mL/min up to 1000 mL/min (see column 7, lines 34-67). Weitzel's disclosure of possible pump rates indicate that the pump 52 is capable of performing at the rate claimed by applicant, meeting the limitations of the claims.

With regard to claim 9, Weitzel illustrates a single blood pump (see FIG 1) for pumping blood from and to the patient.

With regard to claim 10, Weitzel fails to disclose an oxygen tank and an outlet connected to an oxygenator. Weiss discloses an extracorporeal blood treatment system with a blood inlet 134, outlet 136, and membrane oxygenator with an O<sub>2</sub> tank 276 as the oxygen supply and a CO<sub>2</sub> outlet 150 in order to drain spent oxygen and CO<sub>2</sub> from the oxygenator (see FIG 8, column 25, line 60 to column 26 line 68). Therefore, it would have been obvious to someone of ordinary skill in the art at the time the invention was made to add an oxygenator with the associated oxygen supply and venting components disclosed by Weiss in the apparatus disclosed by Weitzel in order to provide a plurality of treatments to replace the function of a patient's damaged blood system and to provide a means for venting CO<sub>2</sub> and unused O<sub>2</sub>, as taught by Weiss.

#### ***Response to Arguments***

3. Applicant's amendment and arguments filed 5 March 2008 have been entered and considered, but applicant's arguments are not persuasive.

Applicant argues that the instantly claimed apparatus with the newly claimed controller is not made obvious by the prior art. However, Weiss discloses a programmable controller. Applicant claims the function of the claimed controller—that it may be programmed in a certain manner. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, it is the position of the Examiner that the controller disclosed by Weiss may be programmed in the manner claimed by applicant, since Weiss specifically discloses that the controller maintains a certain transmembrane pressure, which affects treatment duration and filtration rate—the rate at which fluid is withdrawn from the patient. Accordingly, the instantly claimed invention is unpatentable over the cited prior art.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/  
Primary Examiner  
Art Unit 3761  
12 May 2008